Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: THRIVE-ASD: Telehealth Rapid Intervention for Externalizing Behaviors in ASD

You and your child are being asked to volunteer for a research study. Research studies are voluntary. They include only people who choose to take part. The purpose of this study is to evaluate a time-limited version of Parent Child Interaction Therapy (PCIT) delivered online (telehealth) for young children (ages 2 to 6 years-old) with autism spectrum disorder (ASD) and disruptive behavior problems.

You and your child will complete an in-person visit. If eligible, at the end of this visit, you and your child will be randomly assigned (like flipping a coin) to one of two treatment groups. Meaning that you will be assigned to either receive Tele-PCIT or Treatment-as-Usual. If you are assigned to the Tele-PCIT group, you and your child will complete 10 one-hour telehealth sessions in your home. The sessions will be held once per week for 10 weeks. If you are assigned to the Treatment-as-Usual group, you will receive evaluation feedback, be given behavior management resources, and referred to participate in community services. All participants will be asked to complete two more in-person visits. One within 2 weeks of completing treatment and another 3-months after completing treatment. All in-person study visits will take less than 2 hours to complete. Participation in this study will be completed over the course of about 6 months.

You will be asked personal questions about your child's behavior and your own parenting. You may feel uncomfortable answering some of the questions. If you do not wish to answer a question, you can skip it and go to the next question. A 15-minute parent-child observation at each in-person visit and all therapy sessions will be recorded. If you are not comfortable being recorded, you may choose not to participate. If you are assigned to the Tele-PCIT group, you may feel uncomfortable while receiving coaching and practicing parenting skills during sessions. If you do not feel comfortable with the therapy, you may choose to withdraw from the study at any time. There is a risk of loss of confidentiality with participation. However, your information will be coded to protect your identity.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

About 1 in 54 children in the United States are diagnosed with Autism Spectrum Disorder (ASD). The cause of ASD is still unknown and there is no cure. However, early treatment can have a positive effect. Parent Child Interaction Therapy (PCIT) is a behavioral parent training program. It is one of the most well-validated therapies for children with disruptive behavior problems. PCIT was not originally designed for children with ASD. It is thought to be an effective treatment for disruptive behavior in children with ASD. However, this has not been formally tested in a

large clinical trial. This study will test a time-limited version of PCIT delivered online. The hope is to develop a treatment method that more families can access more easily.

Please read this consent form carefully and take your time making your decision. Please ask the study staff to explain any words or information that you do not clearly understand. You are being asked to participate in this study because your child has ASD and elevated levels of disruptive behavior problems. Approximately 80 families will take part in this study. The study is being conducted at the Medical University of South Carolina (MUSC). The investigator in charge of this study is Rosmary Ros-Demarize, Ph.D. A grant from the Health Resources and Services Administration (HRSA) will sponsor this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1) You and your child will complete an in-person screening visit. Your child's ASD diagnosis will be confirmed by a study clinician. The may include an autism evaluation, if needed. Your child will also complete tests to measure their verbal and language ability and their IQ. This in-person screening visit will take about 2 hours.

2) If eligible for the study, you and your child will then complete an in-person pre-treatment visit the same day. This visit will include a 15-minute recorded observation of you and your child playing together. You will complete a survey about your child's behavior and service use. If your child is enrolled in school, you will be asked for your permission to allow the study staff to contact your child's teacher. The teacher will be asked to complete a standard online survey about your child's behavior in the school setting. You will be asked to provide an email address for your child's teacher. This in-person pre-treatment visit will take about 1 hour.

3) At the end of this visit, you and your child will be randomly assigned to one of two groups: Tele-PCIT or Treatment-as-Usual. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the study staff nor you will make the choice to which group you are assigned. You will be informed of your group assignment.

4) If you are assigned to the Tele-PCIT group: You and your child will complete 10 one-hour sessions of PCIT delivered via telehealth in your home. The sessions will be held once per week for 10 weeks. PCIT is conducted through "coaching" sessions. During these sessions you and your child play while the therapist observes your interactions with your child. You will wear a "bug-in-the-ear" or headset device. The therapist will provide in-the-moment coaching on skills that you are learning to help manage your child's behavior. As part of the therapy you will learn and practice applying new skills. These skills are proven to help children feel calm, secure in their relationships with their parents, and good about themselves. All telehealth sessions will be video recorded for research purposes. PCIT handouts will be provided to you electronically throughout therapy. Prior to each weekly session, you will be asked to complete an online

survey to monitor progress.

At week 6 of treatment, you will complete an online survey about your child's current treatment and services. This will take about 15 minutes to complete.

5) If you are assigned to the Treatment-as-Usual group: At the end of the pre-treatment visit, you will receive evaluation feedback. You will be referred to participate in services available in your community. You will be given a resource guide and access to a self-guided online webinar on behavior management.

   At week 6 of treatment, you will complete an online survey about your child's current treatment and services. This will take about 15 minutes to complete.

6) About 12 weeks after the pre-treatment visit, you and your child will be scheduled for an in-person post-treatment visit. At this visit, you and your child will repeat the 15-minute recorded parent child observation. You will repeat the online survey prior to this in-person visit. Your child's teacher will be asked to complete a standard online survey about your child's behavior in the school setting. The post-treatment online survey will take about 1 hour to complete. The in-person visit will take about 1 hour.

7) About 3 months after the post-treatment visit, you and your child will be scheduled for an in-person follow-up visit. At this visit, you and your child will repeat the 15-minute recorded parent child observation. You will repeat the online survey prior to this visit. Your child's teacher will be asked to complete a standard online survey about your child's behavior in the school setting. The follow-up online survey will take about 1 hour to complete. The in-person visit will take about 1 hour.

If your child is taking certain types of medications and changes to their medications have been made within the last month, start of treatment may be delayed until your child is stable on their medications. The study team will decide when it is best for your family to begin therapy.

If your child displays severe self-injurious behaviors at home or if the study clinician observes such behaviors during the course of the study, therapy may need to be stopped for you and your child's safety.

Participation in this research study is voluntary. You may decide not to participate. You may decide to withdraw from the study at any time. Your decisions will not influence your medical care at MUSC.

C. DURATION

Participation in this study will involve three in-person visits over a period of about 6 months. Participants assigned to the Tele-PCIT group will require 10 one-hour telehealth therapy sessions held once per week over a period of 10 to 12 weeks.

D. RISKS AND DISCOMFORTS

There is a risk of a loss of confidentiality of you or your child's personal information as a result of participation in this study. However, your information will be coded to protect your identity. You will be asked personal questions about your child's behavior and your own parenting. You may feel uncomfortable answering some of

the questions. You may refuse to answer any question that you do not wish to answer. A 15-minute parent-child observation at each in-person visit and all therapy sessions will be recorded. If you are not comfortable being recorded, you may choose not to participate. If you are assigned to the Tele-PCIT group, you may feel uncomfortable while receiving coaching and practicing parenting skills during sessions. If you do not feel comfortable with the therapy, you may choose to withdraw from the study at any time. You will be randomly assigned to one of two treatment groups. The treatment you receive may prove to be less effective than the other study treatment or other available treatments.

E. MEDICAL RECORDS

Information about your or your child's study participation will not be included in your or your child's medical records. This means that neither your or your child's research participation nor any of your or your child's research results will be included in any MUSC medical record. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

F. BENEFITS

The potential benefit to you and/or your child is that the behavioral treatment you may receive may prove to be effective in decreasing disruptive behaviors in your child and decreasing your parental stress. However, this cannot be guaranteed. The results from this study may also lead to benefits for other children with ASD by providing information on a time-limited, cost-effective, and telehealth delivery method of an evidence-based treatment.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid: $50 for participation in the in-person screening visit even if you do not qualify for the study; $50 for participation in the in-person post-treatment visit; and $50 for participation in the in-person 3-month follow-up visit. Your child's teacher will be paid $15 for completing the online survey at each time point. Payment will be in the form of an e-gift card. You will also be reimbursed for parking costs for all in-person visits.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC or USC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you or your child (including identifiable private information) may have all of identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

At the completion of the study, you may request a summary of the study results. This summary will be provided via mail at the address provided by you at the time of the request.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health, the US Department of Defense, or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

O. FUTURE CONTACT

The researchers in charge of this study might like to contact you in the future about other research opportunities for which your child may be eligible. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that your child is injured as a result of participation in this study, you should immediately take your child to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your child's treatment, the Medical University Hospital and the physicians who render treatment to your child will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to your child.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Rosmary Ros-Demarize at 843-876-1516. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ _____

Signature of Person Obtaining Consent Date *Printed Name of Minor Participant

_____

Signature of Adult Participant Date

MUSC
Medical University of South Carolina

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –

A. The following uses do NOT require your authorization, except where required by SC law:
1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.